REMARKS

Claims 1-18 are pending in this application.

Election/Restrictions

The Examiner to whom this application is assigned indicated that the following inventions or groups of inventions are not so linked as to form a single general inventive concept under PCT Rule 13.1. The Examiner stated that the Applicants are required, in reply to this action, to elect a single invention to which the claims must be restricted. Under 35 U.S.C. § 121 and 372, restriction to one of the following groups of inventions is required:

I. Claim(s) 1-5, 7-8, drawn to a composition comprising an effective amount of the HMGB1 protein or functional parts thereof for the treatment of tissue damage and/or to promote tissue repair and regeneration.

II. Claim(s) 1-5, 7-8, drawn to a composition comprising a HMBG1 expressing vectors, for the treatment of tissue damage and/or to promote tissue repair and regeneration.

III. Claim(s) 1-6, drawn to a composition comprising an effective amount of the HMGB1 protein or functional parts thereof and further comprising an effective amount of an anti-inflammatory agent for the treatment of tissue damage and/or to promote tissue repair and regeneration.

IV. Claim(s) 1-6, drawn to a composition comprising a HMGB1 expressing vectors and further comprising effective amount of an anti-inflammatory agent for the treatment

of tissue damage and/or to promote tissue repair and regeneration.

V. Claim(s) 1-10, drawn to a composition comprising an effective amount of the HMGB1 protein or functional parts thereof and further associated to stem cells for the treatment of tissue damage and/or to promote tissue repair and regeneration.

VI. Claim(s) 1-10, drawn to a composition comprising a HMGB1 expressing vectors and further associated to stem cells, for the treatment of tissue damage and/or to promote tissue repair and regeneration.

VII. Claim(s) 11-15, drawn to a composition comprising an effective amount of an antagonist of the HMGB1 protein wherein the HMGB1 antagonist comprises HMGB1 antibodies for the treatment of adverse effects induced by necrotic tissue.

VIII. Claim(s) 11-15, drawn to a composition comprising an effective amount of an antagonist of the HMGB1 protein wherein the HMGB1 antagonist comprises HMGB1 interference RNAs for the treatment of adverse effects induced by necrotic tissue.

IX. Claim(s) 11-15, drawn to a composition comprising an effective amount of an antagonist of the HMGB1 protein wherein the HMGB1 antagonist comprises HMGB1 antisense RNAs for the treatment of adverse effects induced by necrotic tissue.

X. Claim(s) 11-15, drawn to a composition comprising an effective amount of an antagonist of the HMGB1 protein wherein the HMGB1 antagonist comprises HMGB1 synthetic or natural modulators for the treatment of adverse effects induced by necrotic tissue.

XI. Claim(s) 16-18, drawn to a method to promote stem cell migration and/or proliferation in cell culture or in vivo comprising the step of exposing cells to an effective amount of the HMGB1 protein or functional parts thereof.

In response, Applicants respectfully traverse the above restriction.

Under MPEP, there are two criteria for a proper requirement for restriction between patentable distinct inventions: (A) the inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); and (B) there must be a serious burden on the Examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02). If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes independent claims or distinct inventions.

Applicants submit that claims 1-18, Groups I-XI, do not require restriction as they are connected by a single relationship, which is a composition comprising HMGB1, or its antagonists and uses thereof, that connects the claims (MPEP § 802.01). Groups II, IV, and VI are further connected by a vector expressing a HMGB1. Groups VII, VIII, IX, and X are all compositions of HMGB1 antagonists.

In addition, Applicants maintain that the Examiner would not be seriously burdened by searching and examining all of the pending claims in a single application. A search for HMGB1 or its antagonists composition (Group I) will reveal prior art in connection with HMGB1 and other substances or activities (Groups III, V), vectors expressing a HMGB1 (Groups II, IV, and VI), compositions of HMGB1 antagonists (Groups VII, VIII, IX, and X) and method to use of said composition (Group XI, drawn to a method to promote stem cell migration and/or proliferation in cell culture or in vivo comprising the step of exposing cells to an effective amount of the HMGB1 protein or functional parts thereof).

Given the single, searchable unifying relationship, the Examiner would not be seriously burdened by searching and examining the claims of these groups in a single application. (See MPEP § 803.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02. Accordingly Applicants request withdrawal of the restriction of claims 1-18.

Election of Invention

In the event the above discussion does not convince the Examiner to withdraw the Restriction Requirement, Applicants hereby elect Group I, drawn to a composition comprising an effective amount of the HMGB1 protein or functional parts thereof for the treatment of tissue damage and/or to promote tissue repair and regeneration.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

Applicants : BIANCHI, et al.
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No fee is deemed necessary in connection with the filing of this Response. However, if a fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

I hereby certify that this paper is being facsimile transmitted to:

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on the date shown below.

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